

Attorney Docket No.: 6116.200-US
Application No.: 09/757,788
Filed: January 10, 2001
Inventors: Keith Anderson et al.
Via Facsimile No.: 571-273-8300

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing of Claims

Claim 1 (Currently Amended) A liquid formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 μ m.

Claim 2 (Previously presented) The formulation of claim 1 wherein said GLP-1 compound to which a lipophilic substituent is attached is exendin or an analog thereof or a GLP-1 analogue.

Claim 3 (Previously presented) The formulation of claim 2 wherein said GLP-1 compound to which a lipophilic substituent is attached is exendin-3, exendin-4 or Arg³⁴-GLP-1(7-37)-OH.

Claim 4 (Cancelled)

Claim 5 (Previously presented) The formulation of claim 1 wherein said lipophilic substituent is hexadecanoyl.

Claim 6 (Previously presented) The formulation of claim 1 wherein a spacer is present.

Claim 7 (Previously presented) The formulation of claim 6 wherein said spacer is γ -Glu or β -Ala.

Claim 8 (Previously presented) The formulation of claim 1 wherein said GLP-1 compound with a lipophilic substituent attached via a spacer is Arg³⁴Lys²⁶(N^ε-(γ -glutamyl(N^α-hexadecanoyl))) -GLP-

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1(7-37)-OH, Arg¹⁸, Leu²⁰, Gln³⁴, Lys³³ (N^ε-(γ-aminobutyryl(N^α-hexadecanoyl))) Exendin-4-(7-45)-NH₂ or Arg³³, Leu²⁰, Gln³⁴, Lys¹⁸ (N^ε-(γ-aminobutyryl(N^α-hexadecanoyl))) Exendin-4-(7-45)-NH₂.

Claims 9-14 (Cancelled)

Claim 15 (Currently Amended) The formulation of claim 14 1, wherein said formulation is a solution or a suspension.

Claim 16 (Currently Amended) The formulation of claim 14 1, wherein said formulation includes between 0.1 to 100 mg/ml of said GLP-1 compound.

Claim 17 (Cancelled)

Claim 18 (Currently Amended) The formulation of claim 14 1, wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of between 1-5 μm.

Claim 19 (Currently Amended) The formulation of claim 14 1, wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of between 1-3 μm.

Claim 20 (Cancelled)

Claim 21 (Currently Amended) The formulation of claim 20 27, wherein said formulation contains between 50-100 % w/w of said GLP-1 compound.

Claim 22 (Currently Amended) The formulation of claim 20 27, wherein said formulation contains between 75-100 % w/w of said GLP-1 compound.

Claim 23 (Currently Amended) The formulation of claim 20 27, wherein said formulation contains between 90-100 % w/w of said GLP-1 compound.

Claim 24 (Cancelled)

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Claim 25 (Currently Amended) The formulation of claim ~~20~~ 27, wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of between 1-5 μ m.

Claim 26 (Currently Amended) The formulation of claim ~~20~~ 27, wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of between 1-3 μ m.

Claim 27 (New) A dry formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of less than 10 μ m.